

N908

U.S. PATENT APPLICATION OF

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relating to

CONFIGURED AND SIZED CANNULA

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Description

CONFIGURED AND SIZED CANNULA

Technical Field

5 This invention relates to medical instruments for use in surgical procedures and more particularly to a wide-channel cannula that is pre-sized, pre-configured and tailored to conform to the patient's anatomy.

Cross Reference

10 This invention relates to the material disclosed and claimed in a co-pending patent application by the same inventor entitled "Non Cannulated Dilators" and bearing Attorney Docket Number N938 and incorporated herein by reference.

Background of the Invention

15 In one aspect of this invention, the invention considers the anatomical shape of the area of the patient being operated on and tailors the shape of the dilators and the dilator retractor or cannula to accommodate that shape. In

another aspect of this invention, the invention constitutes an improvement over the apparatus and method disclosed and claimed in U.S. Patent No. 6,159,179 granted on December 12, 2000 to the inventor of this patent application and entitled "Cannula and Sizing and Insertion Method" by
5 providing different sizes of the same configuration of dilator retractors.

As is well known by those skilled in this technology, the cannula utilized in the field of minimally invasive surgery is particularly efficacious in performing such spinal medical procedures as laminotomy, medial facetectomy, foraminotomy, nerve root retraction, discectomy and the like,
10 is cylindrically shaped. I have found that a cylindrically shaped cannula is not always ideal for certain surgical procedures and this invention is intended to obviate the problems incidental to a cylindrically shaped cannula and to increase the number of surgical procedures that can be performed by dilation methods by changing the configuration of the retractor tube or cannula. As is
15 apparent to one skilled in this technology, the anatomy of the human spine is not made up of flat surfaces and a purely cylindrical device passed over cylindrical dilators and directed toward the lamina more likely than not settles off of or partly on the bone. When this occurs, a tuft of muscle migrates to or

is left between the bone and the bottom of the retractor and must be removed surgically. Obviously, this surgery is a source of pain and discomfort for the patient and creates an additional surgical step for the surgeon. Moreover, this additional surgery causes additional bleeding and as a consequence, creates an obstruction to the vision of the surgeon. In order to cure the obstruction, the surgeon must address this problem through an electro cautery procedure.

Also apparent to one skilled in this technology is that the pathological target within the patient is often not an equal distance vertically and horizontally. Hence, a surgical procedure may require a surgical approach that for ideal conditions, provides access that is more vertical in orientation than lateral. Obviously, a cylindrical device as has been heretofore available and as disclosed in Patent No. 6,159,179 supra, which is equi-distant from the axis, does not allow for this approach. Thus, in a cylindrical cannula, in order to gain additional vertical access the size of the cannula must be increased the same amount in the lateral direction that it is in the vertical direction. Obviously, the human spine's skeletal structure, i.e. lateral facets and medial spinous process, restricts the amount of lateral space available. In a cylindrical cannula, since a limitation of the lateral space that is available to

such as an ovoid, and that I provide different sizes to meet the anatomical needs of a particular patient. By providing dilators and dilator retractors made in accordance with this invention, these instruments will be able to reach down between the facet joint and the spinous process to gently part muscle tissue and come into closer contact to the bony target. This will reduce or eliminate the need for the surgeon to surgically remove otherwise valuable viable muscle tissue. This will also reduce post-operative pain and inter-operative time (fiddle). In addition to the above, this new design will allow surgeons to address new pathologies in patients that previously would not have been able to undergo a minimally invasive technique. To more fully appreciate the importance of this invention a common example is discussed immediately hereinbelow.

This example considers a patient with multilevel central canal stenosis. To address this patient's pathology, the surgeon may need over 35 millimeters (mm) of vertical access. The typical lateral distance, i.e., space between the spinous process and the facet joint, available at the L4 lamina is 16mm. A 16mm cylindrical retractor would fit tightly against the lamina but even with "wandering" (moving up and down) it would restrict the surgeons ability to

reach much more than the 16mm in vertical access. The only option that is available to the surgeon, heretofore, is to utilize a cylindrical retractor. As explained above, since the equation for a cylindrical retractor mandates that the lateral and vertical expansions are equal, the cylindrical retractor would quickly reach beyond the practical or acceptable size for many, if not most, multilevel patient candidates.

Another embodiment of this invention is the contouring or configuring of the bottom of the retractor in order to meet the requirements of certain operation procedures and/or permit the retractor to be positioned closer to the target. This invention contemplates angling the tip in both a cylindrical and ovoid shaped retractor and/or locating a tunnel in the bottom thereof which allows for a rod or implant to be passed through the distal tip of the cannula and into a pedicle screw.

While much has been accomplished in the medical field to limit tissue disruption, use minimal incisions, reduce the hospital stay and increase the speed in which the patient recovers, this invention is intended to raise the surgical procedure to a higher level. This invention in the field of minimally invasive surgery is particularly efficacious in performing such spinal medical

procedures as laminotomy, medial facetectomy, foraminotomy, nerve root retraction, discectomy and the like.

As discussed in U.S. Patent No. 6,159,179, supra, a typical procedure in performing a lumbar discectomy is to advance a guidewire through a small incision which is advanced to the inferior edge of the superior lamina. A small incision is then made that extends either cranially or caudally. A dilator is then inserted over the guidewire. Larger diameter dilators are sequentially inserted over each other to increase the opening into the body cavity. Typically the guide wire is removed after the first dilator is installed and eventually the dilators are all removed after the tubular retractor has been inserted over the largest of the dilators. Once these procedures are accomplished, the retractor is locked into position by a retractor clamp that is clamped to a retractor clamping arm which is fixed to a rigid member such as the operating table. This provides an unencumbered zone where the surgeon can perform the medical procedure that was intended to be performed. According to the present invention, the dilators, of course will now conform to the configuration discussed above.

Instead of sizing the cannula to the largest depth that is anticipated in

the surgical procedure, the 6,159,179 patent, supra, teaches providing to the surgeon a series of different sizes in a kit so that the surgeon can measure the depth of the cavity of the patient and select the requisite size from the kit. Hence, the surgeon measures the depth by measuring from the exterior of the cavity to the most interior position in the cavity (inferior edge of the superior lamina) and then selects, for example, either a 10 millimeters (mm), 20mm, 30 mm, etc. as the situation requires. The dilator retractor will also have the same cross sectional shape as the dilator, but it may have a predetermined configuration at the distal end. This invention improves the state of the art of spinal surgery by expanding the current boundaries of minimally invasive surgery. This provides a new option to patients that would otherwise be delegated to the more disruptive open muscle stripping surgical approaches. The ovoid design with or without the angled distal tip, allows a surgeon greater vertical access without having to be encumbered by unnecessary lateral access.

Also, it is contemplated within the scope of this invention, that the dilator retractor will be provided in a kit where a given configuration will be provided in a series of dilator retractors that have different lengths, so that the

depth of the cavity of the patient will determine the particular sized dilator retractor that will be utilized for that procedure.

Summary of the Invention

5 An object of this invention is to provide a cannula used in minimally invasive technique that is tailored for a patient and pathology.

A feature of this invention is to provide an ovoid shaped retractor and a complementary shaped dilators. Other configurations that are not cylindrical are contemplated within the scope of this invention.

10 Another feature of this invention is to contour the tip of the distal end of the retractor to match the bone structure in the patient.

Another feature of this invention is to provide an access channel at the distal end of the retractor to allow passage of medical hardware.

15 Another feature of this invention is to provide retractors that are made from a series of predetermined sizes having tailored contouring that the surgeon can select to match the depth of the cavity in the patient made by the dilator.

The foregoing and other features of the present invention will become

more apparent from the following description and accompanying drawings.

Brief Description of the Drawings

Fig. 1 is a schematic illustration of the spine of a patient with the
5 cannula shown in cross section inserted adjacent to the posterior portion of
the vertebra and having superimposed the cannula resting on the bone of a
prior art configuration;

Fig. 2 is an exploded view in perspective of the non cannulated
10 dilator, a series of graduated increased diameter dilators and the cannula or
dilator retractor of this invention;

Fig. 3 is a view in perspective illustrating the non cannulated dilator,
the graduated dilators and the dilator retractor stacked over each other as they
would appear in the patient and the dilator retractor shown in phantom when
the other elements are removed;

15 Fig. 4 is a schematic illustrating an embodiment of this invention where
the dilator retractor is configured with the distal end being slanted to
accommodate the bone structure of the patient;

Fig. 5 is a schematic illustration exemplifying another embodiment of

this invention where the dilator retractor is configured with a tunnel at the distal end;

Fig. 6 is a schematic illustration exemplifying another embodiment of this invention where the dilator retractor is configured in a funnel shape;

5 Fig. 7 is a photocopy of a drawing of the posterior view of the 3rd and 4th lumbar vertebrae with a schematic comparison of a circular in cross section configured prior art dilator retractor and the dilator retractor of this invention;

Fig. 8 is a schematic illustration of a series of different sized dilator retractors sized to accommodate different lengths to fit the anatomical dimensions of patients; and
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Fig. 9 exemplifies another series of varying length dilator retractors as would available to the surgeon.

These figures merely serve to further clarify and illustrate the present invention and are not intended to limit the scope thereof.

15 **Detailed Description of the Invention**

While the preferred embodiment of this invention is described herein, it will be appreciated, as one skilled in this art will recognize, that the

invention, although directed toward non-cylindrically shaped dilator retractors, under certain circumstances, the invention contemplates cylindrically shaped dilator retractors where the bottom or distal end is configured to accommodate the shape of the bone structure of the patient or to accommodate different procedures that are available to the surgeon. As for example, the distal end of a cylindrically shaped dilator retractor may be tunneled so as to allow the insertion of an implant. The terms "cannula" and "dilator retractor" have the same meaning and are used herein interchangeably. The term cavity as used herein means the cavity that is created by the dilators and when the dilator retractor is inserted in this cavity it becomes a working channel for the surgeons use in performing the minimal invasive surgery. While the invention is particularly efficacious for use in performing minimal invasive surgery, as would be obvious to any skilled artisan, this invention would also be useful for other types of surgery.

While in the preferred embodiment the description of this invention details the use of a non cannulated dilator of the type described and claimed in the Cross Reference of this patent application and which is incorporated herein by reference, as one skilled in the art will appreciate, this invention also

contemplates the use of a guide wire for certain surgical procedures.

To better understand this invention reference is made to the prior art configuration of a dilator retractor as viewed in the target area of a patient.

In this example, the patient is inflicted with a herniated disc in the spinal column and the surgeon targets the posterior portion of the vertebra to

perform the surgical procedure. The dilator retractor or cannula 10 is inserted in the body and up to where the distal end rests on the bone structure.

Obviously, there is a space from left to right between the bone and the end of the dilator retractor and as mentioned above, tufts of muscle remains in or

migrates to this area. The surgeon needs to remove this material before performing the procedure for repairing the herniated disc to the discomfort of the patient.

In accordance with one embodiment of this invention and as best seen in Figs. 2 and 3, a series of dilators 12, including the non-cannula dilator 14

serve to enlarge the cavity of the patient by inserting the first dilator or non-cannula dilator 14 into a incision in the skin of the patient and “working” the cannula dilator 14, a tool (not shown) engaging the proximal end by forcing and rocking it through the fibrous and muscle material until it reaches its

target. The cannula dilator is an elongated cylindrical solid body 16 having a tool engaging portion 18 at the proximate end and a pointed tip portion 20 at the distal end. The tip 22 of the pointed tip portion is blunted and slightly rounded so that it is unlike the tip of a common sewing needle, i.e. not razor sharp. The other dilators 12, being progressively shorter in length are all similarly constructed. Namely, they all are hollow so that each progressively shorter dilator passes over the previously inserted dilator and have a tool engaging end portion 24 at the proximate end and a beveled end portion 26 at the distal end that fares into a sharp edge at the bottom thereof. The dilators function is well known and for the sake of convenience and brevity need not be detailed herein. The inventive aspect of the dilators 12 is that they are configured in an elliptical or ovoid shape in cross section and the circumferential dimension between the tool engaging portion 24 and the beveled end portion 26. The hollow portion of each of the dilators 18 are configured to complement the outer surface of the preceding dilator and in the instance of the non cannula dilator 14, the hollow portion of the next succeeding dilator 12 is circular in cross section rather than being elliptical in cross section as are the next succeeding dilators 12. After the dilators 12 have

been inserted into the patient, the dilator retractor 30 is inserted over the last inserted dilator 12 and forced into position, typically with a template or anvil that fits over the proximate end 32 of the dilator retractor 30. The opposite end portion, similar to the dilators 12 is beveled and fares into a sharp edge 34. The hollow portion or straight through bore 26 is contoured identically to the contour of the preceding dilator 12. Fig. 3 demonstrates the positions of the dilators 12 and the non cannula dilator 14 when finally inserted into the patient. As seen in Fig. 3, the dilators 12 and non cannula dilator 14 are removed leaving the dilator retractor 30 in position. Obviously, the dilator retractor 30 affords a wide channel for the surgeon to pass his instruments therethrough allowing the surgeon to perform the surgical procedure while providing sufficient opening to permit the use of a microscope and lighting to view the area of the target.

As mentioned in the Background section of this patent application, in accordance with this invention the distal ends of the dilator retractors are "tailored" to meet certain criteria resulting from the anatomical structure of the target area of the patient. Figs. 4, 5, and 6 exemplify examples of what is meant by the term "tailoring" and while these dilator retractors represent the

preferred embodiment, it will be understood by those skilled in this art that these are merely examples and do not limit the scope of this invention. In Fig. 4, for example, the distal end 40 of dilator retractor 42 is sloped to follow to some degree the slope of the posterior portion of the vertebra. The direction of the slope and the degree of the slope will be predicated on statistical dimensions of these bone structure for a variety of different sized individuals. The cross sectional configuration of the dilator retractor 42 can take any of a number of different shapes, such as elliptical, circular, etc.

Fig. 5 is similar in concept to Fig. 4 except that the dilator retractor 44 includes a cut-out portion 46 at the distal end 48 and side 50 is longer than side 52 or like the dilator retractor 42 depicted in Fig. 4, the bottom portion can be sloped. Since the cut-out portion 46 is made through the side walls and bore of the dilator and dilator retractor it is essentially a cut out of the side walls at diametrical locations at the distal end and hence, defines a lateral passageway or tunnel.

The dilator retractor 54 of Fig. 6 is similar to the dilator retractor depicted in Fig. 4 except that the configuration is funnel shaped. Namely, the upper portion 56 is conically shaped with the wider portion at the proximal

end and fares into the cylindrical portion 58. The distal end 60 is sloped similar to the slope in the dilator retractor 42 depicted in Fig. 4. Obviously, the wider proximal end affords a wider channel that is available for use by the surgeon.

5 It is apparent from the foregoing and particularly with the embodiments depicted in Figs. 4 and 5, the configuration of the dilator retractors can take many shapes, namely cylindrical, elliptical or even polygon shape. Of course, in the preferred embodiment, the thickness of the wall over the major portion of the dilator retractors are uniform.

10 Fig. 7 is included to illustrate the comparison of the heretofore known dilator retractors or cannulas and the dilator retractors or cannulas made in accordance with certain embodiments of this invention. Fig. 7 is a photocopy of a drawing of the lumbar vertebrae showing the posterior view. If the surgeon requires an access provided by the dilator retractor to be say, 35 mm,

15 which is approximately 16 mm larger than the current available dilator retractors, the cylindrically shaped dilator retractor would have to be sized with a 35mm diameter, as depicted by the circle X. Obviously, this sized dilator retractor would not fit into the contour of the vertebral body (spinous

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process) as it would be too wide in the horizontal direction, although sufficiently wide in the vertical direction. In accordance with this invention the major access of the elliptically shaped dilator retractor illustrated by the oval Z is in this example 35 mm and meets the requirement of the surgeon and the minor axis or narrower portion fits into the channel defined by the bone structure of this portion of the spine. In other words, the dilator retractor is contoured to the anatomical configuration of the patient or in other words is "tailored". It being noted that the 16 mm cylindrical dilator retractor, although narrow enough in the horizontal direction, is not sufficient in the vertical direction.

Figs. 8 and 9 exemplify embodiments of this invention where the particular “tailored” shape of the dilator retractor is provided in kits of different lengths to match the depth of the cavity of the working area of the patient. The kit may contain any number of sizes or alternatively, a facility, like a hospital, may inventory a given number of sizes and shapes of the dilator retractor. In the embodiment depicted in Fig. 8 a series of different length dilator retractors or cannulas 70 with the tunnel shaped distal end portion 72 are disclosed as a preferred embodiment and in Fig. 9 a series of different

